IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO PHARMACEUTICALS, LLC, Plaintiffs, v. APOTEX INC., and APOTEX CORP., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

For their Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively "Apotex"), Plaintiffs iCeutica Pty Ltd ("iCeutica") and Iroko Pharmaceuticals, LLC ("Iroko") (collectively, "Plaintiffs"), by their attorneys, allege as follow:

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 9,526,734 ("the '734 patent") and 9,649,318 ("the '318 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2) and 271(a), and for a declaratory judgment of infringement of the '734 and '318 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271(a). Plaintiffs institute this action to enforce their patent rights covering VIVLODEX® brand Meloxicam capsules 5 mg and 10 mg that are approved in the United States by the U.S. Food and Drug Agency ("FDA") for the management of osteoarthritis pain.

THE PARTIES

2. Plaintiff iCeutica Pty Ltd is a company organized and existing under the laws of Australia with a principal place of business at Unit 2, 32 Mumford Place, Balcatta Western Australia 6021.

3. Plaintiff Iroko Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at One Kew Place, 150 Rouse Boulevard, Philadelphia, PA, 19112.

4. Upon information and belief, Defendant Apotex, Inc. is a corporation organized under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L IT9, Canada.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Corp. is a subsidiary of Apotex Inc., and is controlled by Apotex Inc.

7. Upon information and belief, Apotex Corp. acts as the authorized U.S. agent of Apotex Inc. with respect to ANDA No. 210298, and it will work, either directly or indirectly, to manufacture, import, market, and sell the proposed generic Meloxicam capsules 5 mg and 10 mg.

8. Upon information and belief, Apotex Inc. is in the business of, among other things, developing, preparing, manufacturing, packaging, marketing, and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Delaware, through its own systemic, continuous, constant and pervasive actions and through those of its agents and operating subsidiaries, including its subsidiary, Apotex Corp.

9. On information and belief, Apotex Inc. and Apotex Corp. have previously submitted to this Court's jurisdiction. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*,

Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Upon information and belief, Apotex Inc. and Apotex Corp. have also availed themselves of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I 1 (D. Del. Oct. 29, 2003).

10. Apotex Inc. and Apotex Corp. have also purposefully availed themselves of the jurisdiction of this Court by, *inter alia*, asserting counterclaims in lawsuits filed against it in this District. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al.*, Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.*, Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014).

11. Upon information and belief, Apotex Corp. and Apotex Inc. are working in concert to engage in the sale and distribution of generic versions of branded pharmaceutical products, including those manufactured by Apotex Inc., in the United States, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of its agents.

12. Upon information and belief, Apotex Corp. is a licensed drug manufacturer and wholesaler in Delaware.

JURISDICTION AND VENUE

13. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq., including §§ 271(e)(2), 271(a), 271(b) and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

14. This Court has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, the fact that Apotex, Inc. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Iroko Pharmaceuticals LLC, a Delaware company that conducts business in Delaware and derives substantial revenue therefrom and is a Delaware resident, and because Apotex, Inc. has engaged in purposeful systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over Apotex, Inc. for the additional reasons set forth in this Complaint and for other reasons that will be presented to the Court if jurisdiction is challenged.

15. This Court has personal jurisdiction over Apotex, Inc. because, upon information and belief, Apotex, Inc. regularly does business in Delaware and has engaged in a persistent course of purposeful conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

16. This Court has personal jurisdiction over Apotex Inc. because, on information and belief, Apotex Inc., acting in concert with Apotex Corp., has engaged in conduct that reliably predicts Delaware activities by Apotex. On information and belief, Apotex Inc., by acting in concert with Apotex Corp. and submitting ANDA No. 210298, has taken the significant step of applying to the FDA for approval to engage in future activities—including wrongful marketing of its generic drugs—that will be purposefully directed at Delaware.

17. This Court has personal jurisdiction over Apotex, Inc. because Apotex, Inc. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex, Inc. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this

district. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al*., Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.,* Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Apotex Inc. has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I 1 (D. Del. Oct. 29, 2003).

18. This Court also has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

19. This Court has personal jurisdiction over Apotex Corp. as it is incorporated in Delaware. As a domestic corporation, Apotex Corp. is registered to do business with the Delaware Department of State Division of Corporations. This Court also has personal jurisdiction over Apotex Corp. by virtue of, *inter alia*, the fact that Apotex Corp. has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Iroko Pharmaceuticals LLC, a Delaware company that conducts business in Delaware and derives substantial revenue therefrom, and because Apotex Corp. has engaged in purposeful systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over Apotex Corp. for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

20. This Court has personal jurisdiction over Apotex Corp. because, upon information and belief, Apotex Corp. regularly does business in Delaware and has engaged in a persistent

court of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

21. This Court has personal jurisdiction over Apotex Corp. by virtue of*, inter alia*, the fact that Apotex Corp. distributes drug products for sale throughout the United States, including in this judicial district.

22. This Court has personal jurisdiction over Apotex Corp. because, on information and belief, Apotex Corp., acting in concert with Apotex Inc., has engaged in conduct that reliably predicts Delaware activities by Apotex. On information and belief, Apotex Corp., by acting in concert with Apotex Inc. and submitting ANDA No. 210298, has taken the significant step of applying to the FDA for approval to engage in future activities—including wrongful marketing of its generic drugs—that will be purposefully directed at Delaware.

23. The Court has personal jurisdiction over Apotex Corp. because Apotex Corp. has previously been sued in this district and has not challenged personal jurisdiction, and Apotex Corp. has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Senju Pharm. Co. Ltd. et al. v. Apotex Inc. et al*., Civil Action No. 1:07-cv-00779 D.I. 13 (D. Del. Jan. 22, 2008); *Forest Labs. Inc. et al. v. Apotex Corp. et al.,* Civil Action No. 1:14-cv-00200 D.I. 32 (D. Del. May 6, 2014). Apotex Corp. has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Apotex Inc. et al. v. Senju Pharm. Co., Ltd. et al.*, Civil Action No. 1:12-cv-00196 D.I. 1 (D. Del. Feb. 16, 2012); *Apotex Inc. et al. v. Pfizer Inc. et al.*, Civil Action No. 1:03-00990 D.I 1 (D. Del. Oct. 29, 2003).

24. This Court has personal jurisdiction over Apotex Corp. by virtue of, inter alia, the

fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

25. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

26. The ’734 patent, entitled “Formulation of Meloxicam,” issued on December 27, 2016 and names H. William Bosch as the inventor. A true and accurate copy of the ’734 patent is attached hereto as Exhibit A.

27. The ’318 patent, entitled “Formulation of Meloxicam,” issued on May 16, 2017 and names H. William Bosch as the inventor. A true and accurate copy of the ’318 patent is attached hereto as Exhibit B.

28. iCeutica, as assignee, owns the entire right, title and interest in the ’734 and ’318 patents.

29. Iroko is the exclusive licensee to the ’734 and ’318 patents in the United States.

30. Collectively, Plaintiffs are in possession of all rights, title and interest in and to the ’734 and ’318 patents, including all rights to sue and recover for infringement thereof.

31. Iroko is the holder of an approved New Drug Application (“NDA”) No. 20-7233 for Meloxicam capsules 5 mg and 10 mg, sold under the VIVLODEX® registered trademark.

32. In conjunction with that NDA, Iroko has listed with the FDA the ’734 and ’318 patents. The FDA has published the ’734 and ’318 patents in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the “Orange Book”).

33. VIVLODEX ® is covered by at least one claim of the ’734 and ’318 patents.

34. On information and belief, Apotex became aware of the ’734 and ’318 patents no

later than when each patent was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

35. On or about September 21, 2017, Plaintiffs received a letter, dated September 20, 2017, signed on behalf of Apotex by Deepro R. Mukerjee ("Apotex's Paragraph IV Letter").

36. Apotex's Paragraph IV Letter stated that Apotex had submitted, and the FDA had received, an Abbreviated New Drug Application ("ANDA") under section 505(j)(2)(B)(ii) of the FDCA, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Meloxicam capsules 5 mg and 10 mg, a generic version of the VIVLODEX® product, prior to expiration of the '734 patent and '318 patent. The ANDA number for Apotex's application is 210298.

37. On information and belief, Apotex Corp. is the authorized representative for Apotex, Inc. concerning ANDA No. 210298.

38. Apotex's Paragraph IV Letter stated that the '734 patent and the '318 patent are invalid and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

39. Attached to Apotex's Paragraph IV Letter was a statement of the factual and legal bases for Apotex's opinion that the '734 patent and the '318 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

40. In filing its ANDA No. 210298, Apotex has requested the FDA's approval to market a generic version of the VIVLODEX® product throughout the United States, including in this judicial district.

41. On information and belief, following FDA approval of ANDA No. 210298,

Apotex will manufacture, sell, offer to sell, and/or import the approved generic version of the VIVLODEX® product throughout the United States, including in this judicial district.

42. On information and belief, following FDA approval of ANDA No. 210298, Apotex Corp., as the marketing and sales agent for Apotex Inc., will sell and/or offer to sell the approved generic version of the VIVLODEX® product manufactured by Apotex throughout the United States, including in this judicial district.

43. Since receiving Apotex's Paragraph IV Letter, and prior to the filing of the Initial Complaint, Plaintiffs attempted to procure a copy of ANDA No. 210298 from Apotex. Because the terms of the proposed offer would not allow Plaintiffs to meaningfully process the information contained in the ANDA Plaintiffs could not agree to the terms of the original offer. On October 14 and 19, 2017, counsel for Plaintiffs sent Apotex's counsel letters in an attempt to negotiate Plaintiffs' access to ANDA 210298. As of the filing of the Initial Complaint, the parties could not reach acceptable terms for accessing the ANDA.

44. Plaintiffs are not aware of any other means for obtaining information regarding Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Apotex's proposed Meloxicam capsules 5 mg and 10 mg fall within the scope of one or more claims of the '734 patent and/or '318 patent.

45. Because they have been unable to obtain a copy of ANDA 210298, Plaintiffs allege the causes herein based primarily on the representations contained in Apotex's Paragraph IV Letter and the other facts alleged herein.

COUNT I

Infringement of the '734 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

46. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

47. Apotex submitted ANDA No. 210298 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Meloxicam capsules 5 mg and 10 mg throughout the United States. By submitting this application, Apotex has committed an act of infringement of the '734 patent under 35 U.S.C. § 271(e)(2)(A).

48. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '734 patent.

49. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

50. Unless and until Apotex is enjoined from infringing the '734 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

51. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Apotex's ANDA be a date that is not earlier than the expiration date of the '734 patent.

COUNT II

Declaratory Judgment of Infringement of the '734 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

52. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

53. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and

2202.

54. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

55. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 210298.

56. Apotex's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

57. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '734 patent.

58. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

59. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Apotex will constitute direct infringement of the '734 patent.

60. Unless and until Apotex is enjoined from infringing the '734 patent, Plaintiffs will

suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

Declaratory Judgment of Infringement of the '734 Patent Under 35 U.S.C. § 271(b) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

61. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

62. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

63. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

64. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 210298.

65. Apotex's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

66. On information and belief, Apotex will include within the packaging of its proposed generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to use the capsule claimed in the '734 patent.

67. On information and belief, a patient's use of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or

instructions for use of those products will constitute an act of direct infringement of one or more of the claims in the '734 patent.

68. On information and belief, Apotex became aware of the '734 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

69. On information and belief, upon awareness of the '734 patent, Apotex either actually knew of the potential for infringement of one or more claims of the '734 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to use the capsule claimed in the '734 patent.

70. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of active inducement of infringement of the '734 patent.

71. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

72. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Apotex will constitute active inducement of infringement of the '734 patent.

73. Unless and until Apotex is enjoined from infringing the '734 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT IV

Infringement of the '318 Patent Under 35 U.S.C. § 271(e)(2) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

74. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

75. Apotex submitted ANDA No. 210298 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Meloxicam capsules 5 mg and 10 mg throughout the United States. By submitting this application, Apotex Limited has committed an act of infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A).

76. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '318 patent.

77. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

78. Unless and until Apotex is enjoined from infringing the '318 patent Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

79. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Apotex's ANDA be a date that is not earlier than the expiration date of the '318 patent.

COUNT V

Declaratory Judgment of Infringement of the '318 Patent Under 35 U.S.C. § 271(a) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

80. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

81. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

82. There is an actual case or controversy such that the Court may entertain Plaintiffs'

request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

83. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 210298.

84. Apotex's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

85. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '318 patent.

86. The commercial manufacture, importation, use, sale, or offer for sale of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

87. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Apotex will constitute direct infringement of the '318 patent.

88. Unless and until Apotex is enjoined from infringing the '318 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VI

Declaratory Judgment of Infringement of the '318 Patent Under 35 U.S.C. § 271(b) by Apotex's Proposed Generic Meloxicam capsules 5 mg and 10 mg

89. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

90. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

91. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

92. On information and belief, Apotex will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 210298.

93. Apotex's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Apotex has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg.

94. On information and belief, Apotex will include within the packaging of its proposed generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to use the capsule claimed in the '318 patent.

95. On information and belief, a patient's use of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more

of the claims in the ’318 patent.

96. On information and belief, Apotex became aware of the ’318 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

97. On information and belief, upon awareness of the ’318 patent, Apotex either actually knew of the potential for infringement of one or more claims of the ’318 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to use the capsule claimed in the ’318 patent.

98. The commercial manufacture, importation, use, sale, or offer for sale of Apotex’s proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of active inducement of infringement of the ’318 patent.

99. The commercial manufacture, importation, use, sale, or offer for sale of Apotex’s proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs’ patent rights will cause harm to Plaintiffs for which damages are inadequate.

100. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex’s proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Apotex will constitute active inducement of infringement of the ’318 patent.

101. Unless and until Apotex is enjoined from infringing the ’318 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury

of all issues so triable.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) A judgment that Apotex has infringed the ’734 and ’318 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 210298 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Apotex’s proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of infringement of the ’734 and ’318 patents;

B) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Apotex’s ANDA No. 210298 shall be a date which is not earlier than the expiration date of the ’734 patent or the ’318 patent, as extended by any applicable period of exclusivity;

C) An injunction pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’734 and ’318 patents;

D) A judgment declaring that if Apotex engages in the commercial manufacture, use, offer to sell, sale, or importation of Apotex’s generic product disclosed in its ANDA No. 210298 prior to the expiration of the ’734 patent or the ’318 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

E) A judgment declaring that if Apotex engages in the commercial manufacture, use,

offer to sell, sale, or importation of Apotex's generic product disclosed in its ANDA No. 210298 prior to the expiration of the '734 patent or the '318 patent, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);

F) A judgment issued pursuant to 28 U.S.C. § 2201 declaring that if Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's proposed generic Meloxicam capsules 5 mg and 10 mg prior to the expiration of the '734 and '318 patents, it will constitute an act of infringement of the '734 and '318 patents;

G) A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

H) An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

I) Such other and further relief as the Court may deem just and proper.

Dated: October 31, 2017

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